

## PRE-APPEAL BRIEF REQUEST FOR REVIEW

Docket Number (Optional)  
1016720019P

Application Number  
10/803,512

Filed  
March 18, 2004

Art Unit  
3763

Examiner  
Quynh-Nhu Hoang VU

Applicant requests review of the final rejection in the above-identified application. No amendments are being filed with this request.

This request is being filed with a notice of appeal.

The review is requested for the reason(s) stated on the attached sheet(s).

Note: No more than five (5) pages may be provided.

I am the

☐ applicant/inventor.

/Todd W. Wight/

Signature

☐ assignee of record of the entire interest.  
See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed.  
(Form PTO/SB/96)

Todd W. Wight

Typed or printed name

☒ attorney or agent of record.

Registration number 45,218

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☐ attorney or agent acting under 37 CFR 1.34.

October 28, 2008

Date

Registration number if acting under 37 CFR 1.34 \_\_\_\_\_

NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below\*.

☒ \*Total of 1 forms are submitted.

This collection of information is required by 35 U.S.C. 132. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11, 1.14 and 41.6. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Mail Stop AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

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In re Patent Application of:  
Guy ROME

Application No.: 10/803,512

Confirmation No.: 5437

Filed: March 18, 2004

Art Unit: 3763

For: MULTIFUNCTION ADAPTOR FOR AN  
OPEN-ENDED CATHETER

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Examiner: Quynh-Nhu Hoang VU

**ARGUMENTS FOR PRE-APPEAL BRIEF PANEL REVIEW**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Dear Sir:

Applicant respectfully submits the following arguments in support of the Pre-Appeal Brief Request for Review filed concurrently herewith.

In a final Office Action mailed May 30, 2008 (hereinafter, "Office Action"), independent claims 30 and 37 were rejected under 35 U.S.C. § 102(e) as anticipated by US 2004/0193119 to Canaud et al. (hereinafter, "Canaud") and USPN 5,935,112 to Stevens et al. (hereinafter, "Stevens"). In an Advisory Action, dated October 16, 2008 (hereinafter, "Advisory Action"), the Office maintained the rejections of independent claim 30 under 35 U.S.C. § 102(e).

The Office Action also included drawing objections and rejections under 35 U.S.C. § 112, second paragraph. However, these are believed to have been overcome through amendment and argument in the Response dated September 29, 2008, given that neither were mentioned in the Advisory Action. As such, the arguments herein focus on the rejections of independent claims 30 and 37 as anticipated under 35 U.S.C. § 102 by Canaud and Stevens. Applicant respectfully submits to the Panel that neither Canaud nor Stevens anticipates the pending claims for at least the

reasons set forth below and accordingly requests favorable reconsideration and withdrawal of the rejections under 35 U.S.C. § 102(c).

### **I. US 2004/0193119 to Canaud**

Independent claim 30 recites, *inter alia*, “a distal portion of the passageway including a valve having a closed proximal end with a slit and an open distal end.” Independent claim 37 similarly recites, *inter alia*, “a distal portion of a connector housing lumen including a valve having a closed proximal end with a slit and an open distal end.”

In the Response to Arguments section of the Office Action, the Examiner argues that the phrase in Canaud, “although those skilled in the art will recognize that other types of valves may be used” is sufficient for the disclosure of the claimed feature of a “valve having a closed proximal end with a slit and an open distal end.” The Examiner justifies this position by stating that it follows that the Canaud valve “inherently/must have a slit/small hole for fluid flow” and “can be used with other types of valve[s].” By invoking the doctrine of inherency, the Examiner has taken the position that the subject matter of a *particular type and configuration of valve* necessarily/inevitably flows from the comment in Canaud that “other types of valves may be used.” MPEP § 2112. Applicant notes that inherency is not established by mere probabilities or even possibilities. MPEP § 2112. Essentially, the Examiner’s position appears to be that “other types of valves may be used” means that any and all valves ever contemplated in the past or future are anticipated as inherent by disclosure in Canaud of a “bidirectional valve or a duckbill valve.” Applicant respectfully submits that this position is untenable.

Importantly, Applicant is claiming a particular type of valve, namely a “valve having a closed proximal end with a slit and an open distal end,” at least in part because Applicant has discovered particular advantages to overcome recognized issues with prior art valves, such as, for example, those discussed in the application as originally filed at paragraph [0010]. By utilizing the claimed slit valve, a sealing function is provided that distinguishes over other valves, such as those specifically disclosed in Canaud. Further, the slit valve permits threading the catheter over an

inserted guidewire with the adaptor attached (*see* paragraph [0039] of the instant application), which is not a possibility mentioned by Canaud.

Accordingly, Canaud does not show or describe, either expressly or inherently, “a distal portion of the passageway including a valve having a closed proximal end with a slit and an open distal end” (claim 30), or “a distal portion of a connector housing lumen including a valve having a closed proximal end with a slit and an open distal end” (claim 37).

Further, dependent claim 33 recites *inter alia*, “a wall defining the proximal portion of the passageway proximal of the O-ring is tapered.” The Office Action does not state where in Canaud support for this feature can be found. In fact, Canaud actually teaches away from such a configuration by stating that “the passageway 206 has a generally constant diameter between the distal end 202 and the proximal end 204 to promote laminar fluid flow through the passageway 206.” Canaud, paragraph [0039]. Thus, in addition to the deficiency of Canaud discussed above, Applicant submits that the claimed feature of dependent claim 33 is also not shown or described by Canaud.

With further respect to independent claim 37, the Office Action alleges that the Canaud adaptor 420 can be a syringe adaptor. However, while Canaud shows and describes connecting a syringe to luer connector 420 on port 400 (Canaud, paragraph [0066]), there is no showing or description of a connector housing including a *tapered proximal end* with a separate syringe adaptor including a distal end *configured to slide over the tapered proximal end of the connector housing*. In other words, even assuming *arguendo* that the Canaud port could be considered the claimed connector, there is no showing of a tapered end and there is no additional adaptor shown to act as the claimed syringe adaptor. Alternatively, if the port 400 is considered to be the claimed syringe adaptor, there is no showing of a connector over which the syringe adaptor is configured to *slide*.

Further still, independent claim 37 requires that the connector have an opening *configured to receive a proximal end of a catheter*. The Office Action alleges that the claimed connector is shown by component 200, 270 (FIGS. 2-3) or 700 (FIGS. 19-20). However, even assuming *arguendo* that the adaptor 200, 270 or port assembly 700 could be considered the claimed

connector, there is no showing or description of a distal end with an opening configured to receive a proximal end of a catheter. In contradistinction, the Canaud components are configured for insertion into a proximal end of a catheter, as the following passages from Canaud expressly state:

Referring to FIGS. 9 and 10, the distal end 202 of the adapter 200 is inserted into the proximal end 502 of a lumen 504 of a catheter 500. The distal end 202 of the adapter 200 is inserted sufficiently into the lumen 504 such that the catheter 500 extends over the retaining nub 212. Canaud, paragraph [0058], (emphasis added).

The distal portion 702 of port assembly 700 is inserted sufficiently into the lumen such that the catheter extends over the barbs 710. Canaud, paragraph [0072], (emphasis added).

Thus, Canaud does not show or describe the feature of a connector with a distal end having an opening *that is capable* of receiving a proximal end of a catheter, because by definition, if a distal end of the adaptor is to be *inserted into* the catheter lumen, it can't possibly be capable of receiving within its opening that same catheter.

## II. USPN 5,935,112 to Stevens

Independent claim 30 recites, *inter alia*, “a proximal portion of the passageway including an engagement feature configured to connect an end of an instrument to the connector.”

The Office Action cites only to elongated housing 42 as anticipatory disclosure of the claimed connector, but not to any feature that allegedly shows *an engagement feature in a proximal portion of the passageway*. FIG. 2 of Stevens shows an exploded cross-sectional view of the housing 42; however, even if the alleged “proximal portion of the passageway” is identified as bore 86 or compression chamber 88, neither are shown or described as including “an engagement feature configured to connect an end of an instrument to the connector,” as claimed. Thus, Applicant submits that Stevens does not anticipate independent claim 30.

Independent claim 37 recites, *inter alia*, “a syringe adaptor including a distal end configured to slide over the tapered proximal end of the connector housing and a proximal opening configured to receive a male luer portion of the syringe.”

The Office Action alleges that Stevens discloses “a syringe adaptor 46.” Office Action, p. 5. However, with reference to FIG. 2, Stevens identifies reference numeral 46 as a “rotatable end cap” with a proximal end 182 and a distal end 184, the distal end including on an interior surface engagement second threads 202 “for rotational, threaded engagement with first engagement threads 120 on proximal end 84 of housing 42.” Stevens, col. 11, ll. 40-49. The proximal end of the rotatable end cap includes an interior surface 218 that expands radially outward “to form an enlarged retaining mouth 222.”

Thus, assuming *arguendo* that the rotatable end cap 46 of Stevens is a syringe adaptor as alleged in the Office Action, the claimed connector must be viewed as housing 42, because it is the engagement threads 120 of housing 42 over which the threaded end cap 46 is rotated. However, the proximal end of the housing 42 is not shown or described to include a *tapered proximal end* as claimed. In the Remarks to Arguments section of the Office Action, the Examiner argues that the recitation of the syringe adaptor “configured to slide over the tapered proximal end of the connector” is merely intended use. However, the Examiner does not point out where, in Stevens, there is disclosure of a “connector housing including a tapered proximal end” as claimed in independent claim 37. Applicant submits that Stevens does not show or describe at least this feature and therefore does not anticipate independent claim 37.

Applicant’s positions are presented here in summary form. A more developed discussion of the Applicant’s positions are a matter of record in the prosecution history and can be found in the Responses filed April 24, 2008 and September 29, 2008.

Dated: October 28, 2008

Respectfully submitted,

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